K033514

JAN - 6 2004

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PREMARKET NOTIFICATION 510(K) SUMMARY

1. **Submitters Name**: David L Mitchelson

2. **Address**: Charnwood Dynamics Limited
Victoria Mills
Fowke Street
Rothley
Leicestershire
LE7 7PJ
United Kingdom

3. **Telephone No**: +44 (0) 116 230 1060
Facsimile: +44 (0) 116 230 1857

4. **Date Prepared**: 31st October 2003

5. **Trade Name**: Coda cx1 Motion Analysis System

6. **Common Name**: Codamotion System

7. **Classification Name**: System / Optical Position / Movement Recording

8. **Identification of Predicate Device(s):**

CODA mpx30 (K982425)

9. **Device Description**:

Coda cx1 is an optical/electronic system which measures and analyses the 3D position and movement of markers placed on the limbs of patients whose movement function is to be assessed.

Dimensions: 800mm long x 112mm high x 81mm deep

Weight: 5 kg

10. **Intended use**:

The Coda cx1 system has general application to measurement and recording of 3D position and movement, including human movement. It is appropriate for use in assessment of the 3D motion of the limbs and body of patients who have some impairment of movement functions of either a neurological or orthopaedic cause.

11. **Technological characteristics in comparison with predicate device**:

The Coda cx1 system is substantially equivalent to the CODA mpx30 system as a means of measuring the general three dimensional movement of patients, including such activities as walking. Both systems provide a non-intrusive optical method of measuring the movements using infra-red light. Both systems acquire the movement data into a host PC which then analyses and displays the data on graphs and printed reports.

12. **Safety and Effectiveness Summary**:

The Coda cx1 system is designed and manufactured to meet the electrical safety requirements of EN 61010. There is no electrical connection to the patient of any kind. The system does not produce sources of localised heat so no thermal safety hazard arises. The system does not generate any ionising radiation.

The Coda cx1 system has been tested to EN60601-1-2:2002, the Medical electrical equipment – electromagnetic compatibility standard.

The Coda cx1 system has been tested for its effectiveness in measuring 3-D motion and producing graphical and mechanical data on gait and other movements as compared with the predicate device. The resolution at which the data were acquired by the Coda cx1 system and the sampling duration were significantly improved. All other aspects of the system performance were similar to the predicate device.

13. **510 (K) Number**: Not assigned at the time of submission.

14. **Conclusion**:

The Coda cx1 system performs the same measurement functions using substantially similar technology as the predicate device and meets all relevant safety standards. Consequently it is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2004

Mr. David L. Mitchelson
Managing Director
Charnwood Dynamics Ltd
Unit 2, Victoria Mills
Fowke Street
Rothley, Leicestershire
United Kingdom LE7 7PJ

Re: K033514
Trade/Device Name: Coda cx1 Motion Analysis System
Regulatory Class: Unclassified
Product Code: LXJ
Dated: October 31, 2003
Received: November 6, 2003

Dear Mr. Mitchelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K033514**

Device Name: **Coda cx1 Motion Analysis System**

Indications For Use:

The Coda cx1 Motion Analysis System has general application to measurement and recording of 3D position and movement, including human movement. It is appropriate for use in assessment of the 3D motion of the limbs and body of patients who have some impairment of movement functions of either a neurological or orthopaedic cause.

Prescription Use_____ ~~AND~~/OR Over-The-Counter-Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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